AUROQUIL COUGH NIGHTTIME COUGH RELIEF - dextromethorphan hbr and doxylamine succinate solution

Aurohealth LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients (in each 30 mL dose cup)	Purpose
Dextromethorphan HBr USP 30 mg	Cough suppressant
Doxylamine succinate USP 12.5 mg	Antihistamine

Uses

temporarily relieves cold symptoms:

- cough
- runny nose and sneezing

Warnings

Do not use

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- to make a child sleep

Ask a doctor before use if you have

- glaucoma
- excessive phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- trouble urinating due to enlarged prostate gland
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- do not use more than directed
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts.

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses (120 mL) (8 TBSP) per 24 hours
- mL = milliliter; TBSP = tablespoon

adults and children 12 years and over	30 mL (2 TBSP) every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

• when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other information

- each 30 mL dose cup contains: sodium 35 mg
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

alcohol, anhydrous citric acid, FD&C Blue No. 1, FD&C Red No. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or Comments?

1-855-274-4122

Distributed by:

Aurohealth LLC. 2572 Brunswick Pike Lawrenceville, NJ 08648

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 6 FL OZ (177 mL Bottle) AUROHEALTH

Compare to the active ingredients in Vicks[®] NyQuil[®] Cough^{*}

NDC 58602-132-20

AuroQuil COUGH Nighttime Cough Relief

Each dose (per 30 mL) (2 TBSP) of oral solution contains: 30 mg - Dextromethorphan HBr USP (Cough suppressant) 12.5 mg - Doxylamine succinate USP (Antihistamine)

- Cough
- Sneezing, Runny Nose

Alcohol 10%

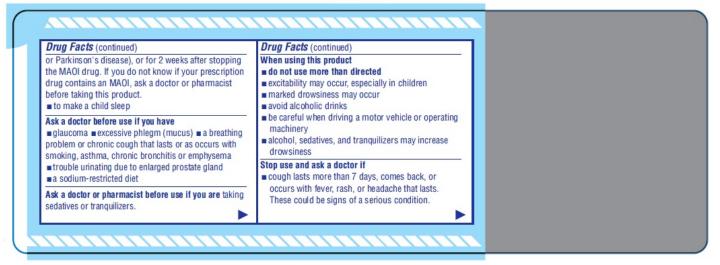
Cherry Flavor

6 FL OZ (177 mL)

Front



Back



Bottom Ply



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 8 FL OZ (236 mL Bottle) AUROHEALTH

Compare to the active ingredients

NDC 58602-132-18

AuroQuil COUGH Nighttime Cough Relief

Each dose (per 30 mL) (2 TBSP) of oral solution contains: 30 mg - Dextromethorphan HBr USP (Cough suppressant) 12.5 mg - Doxylamine succinate USP (Antihistamine)

- Cough
- Sneezing, Runny Nose

Alcohol 10%

Cherry Flavor

8 FL OZ (236 mL)

Front

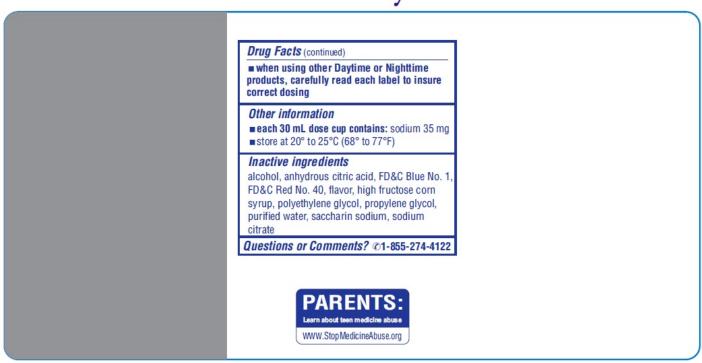
Lift Here for continued Drug Facts **Drug Facts** AUROHEALTH Tamper Evident: Do not use if printed Active ingredients Purpose shrinkband is missing or broken. (in each 30 mL dose cup) Failure to follow these warnings Compare to the active ingredients in Vicks[®] NyQuil[®] Cough* Dextromethorphan HBr USP 30 mg could result in serious consequencesCough suppressant Doxylamine succinate USP 12.5 mg NDC 58602-132-18Antihistamine AuroQu Uses temporarily relieves cold symptoms: ■ cough COUGH runny nose and sneezing *This product is not manufactured or Warnings distributed by Procter & Gamble, Nighttime Cough Relief distributor of Vicks® NyQuil® Cough Do not use Each dose (per 30 mL) (2 TBSP) of oral solution contains: ■if you are now taking a prescription Distributed by: Aurohealth LLC. monoamine oxidase inhibitor (MAOI) (certain 30 mg - Dextromethorphan HBr USP (Cough suppressant) 2572 Brunswick Pike drugs for depression, psychiatric or emotional 12.5 mg - Doxylamine succinate USP (Antihistamine) Lawrenceville, NJ 08648 conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you Cherry do not know if your prescription drug contains Sneezing, Runny Nose an MAOI, ask a doctor or pharmacist before LOT 8 FL OZ (236 mL) licohol 10% taking this product. EXP: ■to make a child sleep

Back

Drug Facts (continued) Drug Facts (continued) Ask a doctor before use if you have Stop use and ask a doctor if cough lasts more than 7 days, comes back, glaucoma or occurs with fever, rash, or headache that excessive phlegm (mucus) a breathing problem or chronic cough that These could be signs of a serious condition. lasts or as occurs with smoking, asthma, If pregnant or breast-feeding, ask a health chronic bronchitis or emphysema ■ trouble urinating due to enlarged prostate professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a a sodium-restricted diet Poison Control Center right away. Ask a doctor or pharmacist before use if you (1-800-222-1222) are taking sedatives or tranquilizers. Directions When using this product ■use dose cup or tablespoon (TBSP) ■ do not do not use more than directed exceed 4 doses (120 mL) (8 TBSP) per excitability may occur, especially in children 24 hours ■ mL = milliliter; TBSP = tablespoon

 marked drowsiness may occur avoid alcoholic drinks be careful when driving a motor vehicle or operating machinery alcohol, sedatives, and tranquilizers may increase drowsiness 	adults and children 12 years and over children 4 to under 12 years children under 4 years	30 mL (2 TBSP) every 6 hours ask a doctor do not use	

Bottom Ply



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 12 FL OZ (354 mL Bottle) AUROHEALTH

Compare to the active ingredients in Vicks[®] NyQuil[®] Cough*

NDC 58602-132-16

AuroQuil COUGH Nighttime Cough Relief

Each dose (per 30 mL) (2 TBSP) of oral solution contains: 30 mg - Dextromethorphan HBr USP (Cough suppressant) 12.5 mg - Doxylamine succinate USP (Antihistamine)

- Cough
- Sneezing, Runny Nose

Cherry Flavor

Alcohol 10%

12 FL OZ (354 mL)



AUROQUIL COUGH NIGHTTIME COUGH RELIEF

dextromethorphan hbr and doxylamine succinate solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-132
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL	

Inactive Ingredients				
Ingredient Name	Strength			
ALCOHOL (UNII: 3K9958V90M)				
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
CHERRY (UNII: BUC5I9595W)				
HIGH FRUCTO SE CORN SYRUP (UNII: XY6 UN3QB6S)				
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)				
SO DIUM CITRATE, UNSPECIFIED FO RM (UNII: 1Q73Q2JULR)				

Product Characteristics				
Color	RED	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				

	Packaging				
II	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
П	1 NDC:58602-132-20	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2015	09/01/2021	
l	2 NDC:58602-132-18	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2015	09/01/2021	
	NDC:58602-132-16	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2015	09/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/27/2015	09/01/2021

Labeler - Aurohealth LLC (078728447)

Registrant - Aurohealth LLC (078728447)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aurohealth LLC		078728447	MANUFACTURE(58602-132)	

Revised: 11/2020 Aurohealth LLC